

Remarks

Claims 1-90 were pending in the subject application. By this Amendment, the applicants have amended claims 29-31 and 33-90 and have cancelled claim 32. No new matter has been added by these amendments. Accordingly, claims 1-31 and 33-90 remain before the Examiner for consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

The applicants appreciate the thorough review conducted by the Examiner and the identification of the numbering issues within the claims. The claims have been renumbered herein consistent with the Examiner's helpful suggestions.

Claims 31, 42-45, 57, 58 and 71-82 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,462,064. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims that are now presented for examination. Specifically, the cited reference does not disclose or suggest each and every element of the applicants' claimed system.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Please note that claim 31 has been amended herein to include limitations from previous claim 32, to which this rejection was not applied. Because the cited reference does not disclose, within its four corners, each and every element of the invention as now claimed in claim 31 (and the claims that depend therefrom) the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 1, 13-15, 21-30, 56 and 59-70 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,462,064 in view of Miffitt *et al.* (US Pat. No. 5,179,288). The applicants respectfully traverse this ground for rejection because the teachings of the '064 patent, even in combination with the '288 patent, do not render obvious the subject invention.

The applicants' invention provides a unique noninvasive transdermal system for detecting an analyte. Advantageously, the applicants' transdermal system can be used by individuals in a self-monitoring capacity. Specifically, the system as set forth in the current applicants' claims, compensate for factors associated with portability that affect accuracy, such as background light changes and unsteady hand-held operation.

Advantageously, because the system compensates for external factors, the system can be used on any skin area suitable for detection including, for example, the arms, underarms, behind the ears, legs, inner legs, fingertips, and torso (specification page 26, second full paragraph). This flexibility of use arises from the unique ability of this system to account for a variety of factors that would otherwise compromise accuracy. Thus, for example, the applicants claim a corrective "means for processing ... to compensate for any shift ... resulting from the detection of ambient light" (specification claim 1). This allows for less than "light-tight fit" as the "[l]eakage of ambient light ... is compensated for by the [claimed] feedback signal and synchronous detection features" (specification page 73, last paragraph).

Desk-top meters, such as disclosed in the cited references, do not have the need to account for variables associated with portability. Therefore, there would be no motivation to modify the device of the prior art to arrive at the current invention. In fact, D'Angelo *et al.* do not provide any guidance in this regard and simply mention analysis using "conventional techniques" (column 1, line 61).

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125,1127 (Fed. Cir. 1984). As expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988).

Furthermore, in *D'Angelo et al.*, the systems rely upon, among other things, a multilayered gel matrix which includes a separate activation gel layer and a separate collection gel layer disposed below the activation gel layer, an osmotic flow enhancer, such as ethyl ether, to facilitate the collection of an analyte fluid, and a chemistry detection methodology to aid in the visual or electronic determination of an analyte under investigation. Ethyl ether, however, is a known skin irritant which is flammable and explosive.

Miffit *et al.* teach a specific method of compensating for extraneous light within their device. This detection methodology differs from the features of the applicants' invention. Based on the teachings of Miffit *et al.*, one of ordinary skill in the art would simply construct a door to the stationary unit, as was done by Miffit *et al.* (column 8, lines 26-27), to reduce any effect of ambient light. In fact, the only "ambient" light accounted for is the "electrical ambient light effects" in the unit (column 7, line 21).

Additionally, the corrective circuit of Miffit *et al.* is also meant for the measurement adjustment due to potential variations of LEDs used in the device (column 7, lines 5-7). These disclosures of Miffit *et al.* do not render obvious the current applicants' corrective means for processing and the generation of the feedback signal for negating the deleterious effects of ambient light.

The devices in the cited references are not intended to operate in the same manner as the subject invention. The cited references differ in the method of use and there would be no reason for the skilled artisan to apply these teachings to the current applicants' methods. Further, the means by which the applicants correct for external factors are by no means disclosed or suggested by the cited references. Thus, the skilled artisan would have neither guidance nor motivation to arrive at the invention claimed.

An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

The mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007). The skilled artisan would not have had a reason to modify the teachings of the cited references to, for example, correct for ambient lighting as the current applicants have done.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a) based on D'Angelo *et al.* in view of Miffit *et al.*

Claims 37, 46-55 and 83-90 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,462,064 in view of Ligg Pty. (WO 83/00926). The applicants respectfully traverse this ground for rejection because the cited references, either taken alone, or in combination, do not disclose or suggest the advantageous system claimed by the current applicants.

The shortcomings of the '064 patent, as that patent relates to the current invention, have been discussed above. The Ligg Pty. reference does not cure, or even address these deficiencies. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based on D'Angelo *et al.* in view of Ligg Pty.

Claims 2-5 have been rejected under 35 U.S.C. §103(a) as being unpatentable over D'Angelo *et al.* and Miffit *et al.* as applied to claim 1 above, and further in view of Cheung *et al.* (US Pat. No. 4,913,150). The applicants respectfully traverse this ground for rejection because the cited references, either taken alone, or in combination, do not disclose or suggest the advantageous system claimed by the current applicants.

The shortcomings of the primary references, as those references relate to the current invention, have been discussed above. The Cheung *et al.* reference does not cure, or even address, these shortcomings.

Specifically, the inclusion of the corrective “means for processing ... to compensate for any shift ... resulting from the detection of ambient light” (specification claim 1) makes the current system non-obvious. The addition of the “temperature sensor” or “temperature compensator” to the device of claim 1 merely supplements the novel and nonobvious reflectometer claimed by the applicants. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over D’Angelo *et al.* and Miffit *et al.* as applied to claim 1 above, and further in view of Farkas *et al.* (US Pat. No. 5,477,853). The applicants respectfully traverse this ground for rejection because the cited references, either taken alone, or in combination, do not disclose or suggest the advantageous system claimed by the current applicants.

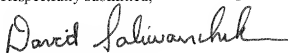
The deficiencies of the primary references, as those references relate to the current invention, have been discussed above. The Farkas *et al.* reference does not cure, or even address these deficiencies. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based on D’Angelo *et al.* and Miffit *et al.* and further in view of Farkas *et al.*

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "David R. Saliwanchik". The signature is fluid and cursive, with a long horizontal stroke at the end.

David R. Saliwanchik  
Patent Attorney  
Registration No. 31,794  
Phone: 352-375-8100  
Fax No.: 352-372-5800  
Address: P.O. Box 142950  
Gainesville, FL 32614-2950